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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,735	11/17/2005	Louis Ptacek	007180-74 US	3966

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EXAMINER	
PROUTY, REBECCA E	
ART UNIT	PAPER NUMBER
1652	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,735	PTACEK ET AL.	
	Examiner	Art Unit	
	Rebecca E. Prouty	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *9-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 May 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 1-8 in the reply filed on 5/19/08 is acknowledged as is applicants request of 5/20/08 to withdraw the election. However, the Office has no provisions for withdrawing a paper from the Official record and thus an action by the Office is necessary. The traversal is on the ground(s) that all claims share the linking feature of the discovery of genetic variants of the casein kinase I delta and casein kinase I epsilon genes and the resultant protein products of the same. This is not found persuasive because genetic variants of these genes (although different from the specific variants taught in the instant application were in fact known in the art (see for example database SNP entries rs1130774 and rs1140432) Thus applicants asserted linking feature is not a special technical feature as defined by PCT Rule 13.2 and the claims do lack unity of invention. Furthermore, the specific polynucleotides recited are not special technical features for the reasons presented in the previous restriction.

The requirement is still deemed proper and is therefore made FINAL.

Claims 9-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 5/19/08.

Claim 1 is objected to because of the following informalities:

- "polynucleotide coding for" in parts (a) and (b) should be "polynucleotide encoding". Appropriate correction is required.
- "a polypeptide consisting of the amino acid sequence of SEQ ID NO:7" should be "the polypeptide consisting of the amino acid sequence of SEQ ID NO:7" as there is only a single polypeptide consisting of the amino acid sequence of SEQ ID NO:7 not more than one as the indefinite article "a" implies.

Appropriate correction is required.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (upon which claims 2-8 depend) is confusing in the recitation "a degenerate polynucleotide" as it does not define to what polynucleotide the claimed polynucleotide must be degenerate. Furthermore, assuming that applicants intended

degenerate to SEQ ID NO:5, parts (a) and (b) are identical in scope and redundant

Claim 1 (upon which claims 2-8 depend) is confusing in the recitation "a polypeptide coding for the amino acid sequence " as polypeptides do not encode amino acid sequences

Claim 1 (upon which claims 2-8 depend) is confusing in the recitation "a polynucleotide complementary to the polynucleotide of (a) or (b)" as it is unclear if the recited complementary polynucleotides must be the full length complements are may include fragments also. As part (d) of the claim clearly intends to recite fragments it is assumed for further examination that applicants intended this portion of the claim to recite full length complements only. If applicants intended the recited complementary polynucleotides to be the full length complements, it is suggested that the claim be amended to recite "a polynucleotide complementary to the full length of the polynucleotide of (a) or (b)".

Claim 1 (upon which claims 2-8 depend) is confusing in the recitation "including nucleotide 446" as the number is unclear absent a reference sequence to which it refers. It is suggested that this be amended to "including the nucleotide corresponding to nucleotide 446 of SEQ ID NO:5".

Claims 7 and 8 are confusing in the recitation of "allowing the cells to express" as it is unclear what actions this corresponds to. It is suggested that this be amended to "culturing the cells to express".

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid consisting of a fragment of at least 15 nucleotides of SEQ ID NO:5 including nucleotide 446, does not reasonably provide enablement for any nucleic acid comprising a fragment of at least 15 nucleotides of a nucleic acid encoding SEQ ID NO:7 including the nucleotide corresponding to nucleotide 446 of SEQ ID NO:5. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-3 and 5-8 are so broad as to encompass any nucleic acid comprising a fragment of at least 15 nucleotides of a nucleic acid encoding SEQ ID NO:7 including the nucleotide corresponding to nucleotide 446 of SEQ ID NO:5 and vectors and host cells comprising said nucleic acids. Thus the sequence can have any number of variations from SEQ ID NO:5 and can be as short as 15 nucleotides encompassed within any amount of additional sequence. The scope of the claims is not

commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acids encompassed. The disclosed use for the claimed nucleic acids is as probes within a diagnostic procedure to determine the presence of absence of a particular casein kinase 1 delta (CSNK1D) variant. However in view of the fact that the disclosed variants is a single nucleotide polymorphism, only fragments of the CSNK1D gene which are 100% identical to a portion of SEQ ID NO:5 including nucleotide 446 would be suitable probes for distinguishing the presence or absence of that allele as nucleic acids with other variations or embedded within substantial amounts of additional sequence would not hybridize to distinct alleles differentially. Since the nucleotide sequence of a probe determines its structural and functional properties, predictability of which variants of a known sequence can be used as a probe for a given target sequence requires a knowledge of and guidance with regard to the ways in which the probes' structure relates to the desired function. However, in this case the disclosure is limited to the structure of the nucleic acids of SEQ ID NO:5 and the disclosure of the particular polymorphisms of nucleotide 446.

While methods of modifying nucleic acids are well known in the art, it is not routine in the art to screen for multiple

substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a probe's sequence where modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any probe and the result of such modifications is unpredictable. Furthermore, the usefulness of any variant of a gene as a probe depends of the specificity of the probe for the target and the ability to exclude non-target nucleic acids from reacting therewith. In the instant case the scope of nucleic acids encompassed in the claims is so broad that the vast majority of claimed nucleic acids within the scope of the claims could not be used as taught. The specification fails to provide guidance for the selection of useful nucleic acids within the scope of the claims beyond guiding one to specific fragments of SEQ ID NO:5 which include nucleotide 446. However, the scope of claimed nucleic acids is vastly broader with little or no expectation of successful use thereof provided by the specification.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acid comprising a fragment of at least 15 nucleotides of a nucleic

acid encoding SEQ ID NO:7 including the nucleotide corresponding to nucleotide 446 of SEQ ID NO:5. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of nucleic acids having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmetterer.

Schmetterer teach a nucleic acid comprising the nucleotide sequence TGTTTGGCTTTGACAC (residues 180-195 of Figure 1) which is identical to the complement of residues 438-453 of SEQ ID NO:5, vectors comprising said nucleic acid, the transformation of these vectors into a host cell and expression of the nucleic acid in said host cell to produce the protein encoded by said

nucleic acid. As such Schmetterer anticipate all of the instant claims.

Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. The prior art does not teach the specific allelic variant of the CSNK1D gene of SEQ ID NO:5 nor provide any motivation for altering the known variants at residue 446.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed, can be reached at (571) 272-0934. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
Art Unit 1652